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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,533	07/11/2002	Nigel Robert Arnold Beeley	238/086 PCT/US.	1938

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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/554,533	BEELEY ET AL.	
	Examiner	Art Unit	
	Samuel W. Liu	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-57* is/are pending in the application.

4a) Of the above claim(s) *63-65,72 and 73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-62, 66-71 and 74-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 55-75 are pending.

The amendment filed 10/29/06 which amended claims 55, 70 and 74, and cancels claims 1-54 has been entered. Claims 63-65 and 72-73 are withdrawn from further consideration (se the Office action mailed 7/21/06). Thus, claims 55-62, 66-71 and 74-75 are under examined in this Office action.

Priority

This application is a 371 of PCT/US9824210 filed 11/13/1998. Based on this PCT application, Applicant's claim for the benefit of a prior-filed application 60065442 filed 11/14/1997 under 35 U.S.C. 119(e) is acknowledged.

Withdrawal of objection/rejections

- The objection to the specification and claims is now withdrawn in light of the amendment to the specification.

- The rejection under 35 U.S.C. 112, second paragraph, to claims 56, 58, 61 and 71 is withdrawn (these claims are now objected to). The rejections to claims 70 and 74 is withdrawn in light of the amendment to the claims. The rejection to claim 71 is withdrawn in light of that the applicants' argument (on page 31) thereof is persuasive.

- The rejection under 35 USC 102 to claims 55, 57, 59-60, 62, 66 and 69 by Young et al. is now withdrawn in light of that the Young's SEQ ID NO:32 is the peptide consisting of 39 not 38 (instant claims) amino acids. The rejection under 35 USC 103 by Young et al. are also withdrawn because the Young et al. patent is not the prior art herein.

• The rejection under 35 USC 112, first paragraph to claims 55-62, 66-69, 70-71 and 74-75 is now withdrawn.

New-Objection to claims

• *Sequence Compliance*

Claims 55-62, 66-71 and 74-75 are objected to because the peptide formula set forth in claim 55 and formula in claim 66 are disclosed without SEQ ID NO identification. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to **fully** comply with the requirements of 37 C.F.R. ∋ 1.821 through 1.825; Applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990).

If the noted sequences are in the sequence listing as filed, Applicants must amend the specification to identify the sequences appropriately by SEQ ID NO. If the noted sequences are not in the sequence listing as filed, Applicants must provide (1) a substitute copy of the sequence listing in both computer readable form (CRF) and paper copy, (2) an amendment directing its entry into the specification, (3) a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. ∋ 1.821 (e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d), and (4) any amendment to the specification to identify the sequences appropriately by SEQ ID NO.

• Claims 56, 58, 61, 66-69 and 74-75 are objected to for containing non-elected subject matter. Claims 56 and 67 recite "Xaa_2 is Ser"; claims 58 and 68 recites "Xaa_3 is Asp"; and claim 61 recites "Xaa_{28} is Ala"; these recitations do not read on the elected SEQ ID NO:29.

Maintained-Claim Rejections - 35 USC § 101

35 U.S.C. §101 states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 55-62, 66-71 and 74-75 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 55 and 66 and dependent claims thereof, as written, do not sufficiently distinguish over other peptide or polypeptide or protein, as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor. See MPEP 2105.

Applicants' response to the rejection under 35 USC 101

On page 29, the response filed 10/9/06 argues that as the Examiner does not point to any naturally-occurring peptides that fall within the scope of the claims, the rejection should be withdrawn.

The applicants' argument is found unpersuasive because factually proving whether the questioned peptide is naturally occurring is not required for the above rejection here. Moreover, the peptide (genus) of claim 55 reads on naturally occurring exendin-3 peptide (instant SEQ ID NO:1) except a single C-terminal serine residue which is not in exendin-3. naturally occurring exopeptidase hydrolyses a single amino acid from the end of peptide chain. With C-terminal serine hydrolyzed, the exendin-3 peptide has Pro-Pro-Pro at C-terminus. Thus, the exendin-3

(without c-terminal serine) might exist naturally. It has been shown that peptide containing C-terminal Pro-Pro is resistant to proteolysis (see Peeters et al. (1983) *J. Biol. Chem.* 258, 14206-14211, page 14206, the right column). It is thus burden for applicants to show this exendin-3 peptide does not exist naturally.

Based on the above discussion, it is deemed that the claims as written do not sufficiently distinguish over other peptide or polypeptide existing naturally. Therefore, the rejection is maintained.

New- Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 55, 57, 59-60, 62, 66, 69-70 and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Beeley et al. (US Pat. No. 6956026 B2).

In Example 61 (col. 32), Beeley et al. teach an exendin agonist peptide (38 amino acids) of SEQ ID NO:63 which reads on instant the peptide formula of claim 55, which anticipates claim 55.

Residue 2 (instant Xaa2) of the Beeley's peptide is Gly, which also anticipates claim 57.

Residue 14 (instant Xaa14) of the Beeley's peptide is Leu, which also anticipates claim 59.

Residue 25 (instant Xaa25) of the Beeley's peptide is Phe, which also anticipates claim 60.

The C-terminus of the Beeley's peptide is NH_2, which also anticipates claim 62.

In Example 60 (col. 32), Beeley et al. teach an exendin agonist peptide (38 amino acids) of SEQ ID NO:62 which reads on the instant peptide formula of claim 66, which anticipates claim 66.

The C-terminus of the above Beeley's peptide is NH_2, which anticipates claim 69.

At col. 7, line 61-63, Beeley et al. teach that the exendin agonist compound has formula of SEQ ID NO:4 (consisting of 38 amino acid residues, see columns 71-76). At abstract and col. 4, lines 3-7, Beeley et al. teach treatment of a disorder state comprising administering to a subject in needed thereof said exendin agonist compound; and, at col. 4, lines 26-28, Beeley et al. further teach that said disorder state is Type II diabetes. Therefore, Beeley et al. teach the methods of instant claims 70 and 74.

New-*Claim Rejections - 35 USC §103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 55-62, 66-70 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beeley et al. US Pat. No. 6956026 B2).

The rejection to claims 55, 57, 59-60, 62, 66, 69-70 and 74 has been discussed above.

Yet, Beeley et al. in their patent do not expressly teach Xaa2 and Xaa14 are Ser and Leu, respectively in SEQ ID NO:63, and, Xaa2 and Xaa3 are Ser and Asp, respectively in SEQ ID NO:62.

Beeley et al. do teach a generic peptide formula (SEQ ID NO:4, see col. 7, lines 61-63) which has the identical length to that of SEQ ID NOs: 62 and 63. The peptides of SEQ ID NOs:62 and 63 read on said formula (see the above); wherein Xaa2, Xaa3 (read on claims 56, 58, 67 and 68) are Ser and Asp, respectively, and wherein Xaa28 is Ala (read on claim 61). The

species in each "Xaa" are limited to 2-4 amino acids, e.g., Xaa2 is Ser, Gly, Ala or Thr, Xaa3 is Asp, Ala or Glu, and Xaa28 is Ala or Asn. Hence, the peptides having modifications at residues 2 and 3 (for SEQ ID NO:62) and modifications at residues 2, 3 and 28 (for SEQ ID NO:63) are **obvious variation** of the disclosed SEQ ID NOs:62 and 63 peptide thereof. Therefore, the above Beeley et al., teaching are applied to claims 56, 58, 61, 67 and 68.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the exendin agonist compound according to the Beeley et al. SEQ ID NO:62 and 63 with modifications at amino acid residues 2, 3 and 28 discussed above. This is because Beeley et al. have taught that the peptides having structural feature set forth in SEQ ID NO:4 are exendin agonist compounds (see col. 7, lines 61-63), and because Beeley et al. also taught the useful processes for (i) synthesis of the peptides, (ii) purification of the peptide thereof (see col. 12, lines 36-67 and Examples 61-62), and formulation of the peptides into the pharmaceutical composition for treating disorder, e.g., diabetes (see columns 13-14). Thus, one skilled in the art would have readily implemented the modifications thereof (*note that Xaa2 (Ser, Gly, Ala or Thr), Xaa3 (Asp, Ala or Glu) and Xaa28 (Ala or Asn) are considered to be small group [limited] of species which would not place any undue level of experimentation to the skilled artisan*), and synthesized, purified and formulated the purified peptide(s) into the pharmaceutical composition for treating diabetes with reasonable success.

Therefore, the claimed invention was *prima facie* obvious to make and use the invention at the time it was made.

*Examiner note: US Pat. No. 6956026 is not a double patenting reference because the methods (the method of reducing food intake and the method of reducing appetite) disclosed in 6956026 is different form the instant method of treating diabetes.

Conclusion

No claims are allowed.

Discussion of the art

The prior art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

• Du Bois et al. (US Pat. No. 6399601 B1) teach that exendin-4 can be administered in combination with insulin (see col. 24, lines 18-67) which reads on the limitation of instant claims 71 and 75. This reference, however, is not an obviousness art against the claims because the earliest priority of this patent does not antedate the priority date (11/14/1997) of the instant application.

• Hiles et al. (US Pat. No. 6506724) teach administering exendin-4 in conjunction with insulin for treating gestational diabetes (see col. 1, lines 8-11). This reference is not the prior art applicable to claims 71 and 75 because it does not antedate the current invention.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is571-272-0949. The

examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, Ph.D.
Art Unit 1656, Examiner
November 28, 2006

KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER